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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,359	12/21/2001	Anneli Attersand	10806-156	4324
24256	7590	12/31/2003	EXAMINER	
DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			WAX, ROBERT A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,359	ATTERSAND, ANNELI	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. Claims 1, 4-7, 9 and 10 are again rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection was explained in the previous Office action.

2. Claims 1, 4-7, 9 and 10 are also again rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 4-7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The language, "consisting essentially of" is indefinite in the context of this patent application. The term is not defined in the specification and, while that phrase has a well-established meaning in the composition art has no art-accepted meaning in the compound art. In the composition art "consisting essentially of" excludes "those [materials] that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). No such definition applies to compounds. This rejection may be overcome by amending "consisting essentially of" to "comprising" or "consisting of".

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 1 is again rejected under 35 U.S.C. 102(b) as being clearly anticipated by Birren et al.

This rejection was explained in the previous Office action.

Claim Rejections - 35 USC § 103

7. Claims 1, 4-7, 9 and 10 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Albertini et al. in view of Birren et al.

This rejection was explained in the previous Office action.

Response to Amendment

8. Examiner appreciates the removal of the "http:www." portions of the Internet addresses and capitalization of each noted trademark. Cancellation of claims 2, 3 and 8 is noted, applicant may, of course, pursue these claims in a divisional application.

Applicant argues the rejection for lack of utility by stating that the statements in the specification are sufficient to establish a specific, substantial and credible utility for the nucleic acids claimed. Examiner must respectfully disagree. The prediction on page 1 of the specification is not enough to establish utility. Similarly, the statement that the genes are expressed in germ cells and in nervous system in Example 3 gives no clue as to their actual function. The specification states, "the nucleic acid molecules . . . are proposed to be useful for differential identification of the tissue(s) or cell types(s) present in a biological sample and for diagnosis of diseases and disorders, including disorders of the central nervous system." This speculation does not constitute disclosure of a specific, substantial and credible utility. If it were shown that the nucleic acids were expressed exclusively in a particular cell type then the detection of the polypeptide encoded by that nucleic acid would be useful to identify that cell type. Such is not the case here, much less the ability to use the nucleic acid or polypeptide for diagnosis. Example 9 explains how to go about determining the function but gives no

information as to any results of such studies. More than proposed utilities are required in order to establish that an invention has a specific, substantial and credible utility; in the absence of actual data the rejection is maintained.

Applicant argues the anticipation rejection by stating that Birren et al. do not show the claimed sequence, even though their sequence includes a portion of the nucleic acid molecules identified as SEQ ID NO. 1. Again, Examiner must disagree. Birren et al.'s sequence includes the claimed sequence since a sequence embedded in a larger sequence is comprised by that sequence. The meaning of "comprising" was reversed in the previous Office action. Comprising is nonlimiting and means that what is specified in the claim must be in the reference but additional components (or sequences) are not excluded. Applicant has attempted to eliminate Birren et al. by amending the claims to read "consisting essentially of". However, since that phrase is indefinite in this context, the claim is interpreted to still recite "comprising". Notwithstanding the above considerations, Birren et al. read exactly on part b of claim 1, since the sequence in the reference would hybridize to nucleotides 93-740 of the claimed sequence (the coding region). This rejection could be overcome by specifying that the nucleic acid must hybridize along its full length to the coding region, provided basis for such amendment exists in the specification.

Applicant argues the obviousness rejection by stating that neither Albertini et al. nor Birren et al. teach the claimed nucleic acid sequence and that no suggestion is provided by Birren et al. to combine with Albertini et al. "Examiner disagrees with this argument as well. Birren et al. do indeed teach a sequence within the scope of claim 1.

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Albertini et al. is a single example of what those of ordinary skill in the art do with nucleic acids, they express the encoded proteins by inserting the nucleic acid into a vector, place the vector in a host cell and culture the host cell to produce the protein. Thus, the rejection under 35 USC 103(a) is maintained.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (703) 308-4471. The examiner can normally be reached Monday - Friday, 9:00 - 5:30. After January 8, 2004 the new phone number will be (571) 272-0623.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Robert A. Wax', is positioned above the printed name and title.

Robert A. Wax
Primary Examiner
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